FDA 510(k) Premarket Notification

K031292 MODIFICATION TO FOSSA URETERAL STONE SWEEPER

CLEARED

May 22, 2003
29 days to decision

K031292 · Product code: **FAD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k031292/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stent, Ureteral (FAD)
Date received	Apr 23, 2003
Decision date	May 22, 2003
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Fossa Medical, Inc.**
Location	Ayer, MA, US
Contact	PAMELA PAPINEAU
510(k) history	3 submissions · 3 cleared · 2003-2008